



**Presidential Commission**  
*for the Study of Bioethical Issues*

**TRANSCRIPT**

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Meeting 16, Opening Remarks and Session 1

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CHAIR GUTMANN: Welcome, everybody. I think we're all here. Several of our members could not attend this meeting and maybe are listening, but welcome, everybody, to our Bioethics Commission meeting.

I'm Amy Gutmann, President of the University of Pennsylvania and Chair of the Presidential Commission for the Study of Bioethical Issues. On behalf of myself and our Vice Chairman, Jim Wagner, who is the President of Emory University, I would like to welcome you to our 16th meeting.

Before we continue, let me note the presence of our Designated Federal Officer, Bioethics Commission Executive Director, Lisa M. Lee, and, Lisa, please stand so everyone can identify you.

Thank you very much.

I'd also like to ask the Bioethics Commission members to introduce themselves, beginning with Nita.

DR. FARAHANY: I'm Nita Farahany, Professor of Law and Philosophy and Genome Sciences and Policy at Duke University.

DR. KUCHERLAPATI: I am Raju Kucherlapati. I'm in the Department of Genetics and in Medicine at Harvard Medical School.

DR. MICHAEL: Nelson Michael. I'm an HIV researcher at the Walter Reed Army Institute of Research.

DR. ALLEN: I'm Anita Allen. I'm Vice Provost for Faculty at the University of Pennsylvania, where I'm also Professor of Law and Professor of Philosophy.

DR. HAUSER: Stephen Hauser, Chair of Neurology, Professor of Neurology at the University of California-San Francisco.

DR. GRADY: And I'm Christine Grady. I'm the head of the Department of Bioethics at the National Institutes of Health Clinical Center.

CHAIR GUTMANN: Thank you very much.

Today and tomorrow what we're going to do is continue work in response to President Obama's charge to review the ethical issues associated with the conduct and implications of neuroscience research.

Our overarching goal here, as you'll hear as we present some of our thinking on this, is to make sure that very early on in the development of neuroscience we integrate professional ethics communication, accurate communication, about neuroscience to the public to increase that understanding, and also ethics integration into neuroscience research.

In late January, we published a request for public comment in the Federal Register to collect information from a wide range of stakeholders on neuroscience and related ethical issues. I encourage anyone interested in providing input to the Commission to review and respond to that request. It's available on our Website, [bioethics.gov](http://bioethics.gov). All comments received by the deadline, which is April 1st, 2014, will be reviewed and logged.

Public comments have always played a very important part in our deliberations, and I'm certain the comments we receive as part of this project will be no different.

On a related note, before we get started, I would like to take a moment to explain how we will take public comments at this meeting. At the registration table out front there are comment cards, but staff members of the Commission here also have cards.

Could the staff members please stand up?

They all have cards. So just ask them, and they're happy to give you a card.

Now, we ask that you write down your comments on one of these cards, hand the card to the Commission staff member, and the Commission staff members will give me cards as we proceed. All comments, whether we read them today -- sometimes we have time for more, sometimes for less -- we will read them all and we actually take all of them into account.

So thank you in advance for participating in this meeting, and I want to turn the table over to Dr. Wagner for some comments.

Jim.

VICE CHAIR WAGNER: Actually I have no comments except to thank our staff again for preparation for this meeting.

Welcome to my Commission colleagues, our Commission colleagues together, and to the guests that are here, and I think we ought to get to work.

CHAIR GUTMANN: Great. Thank you.

So we want to issue a preliminary report in order to give a timely response to President Obama's charge, and in order to do that we formed two working group, small working groups, consisting of Commission members, and they engaged in preparatory work to inform the Bioethics Commission's discussions and deliberations.

One working group, the Research and Integration Working Group, is focused on the first part of our charge, and that is, and I quote, "identify proactively a set of core ethical standards to guide neuroscience research," very foundational and basic.

The second working group, the Application and Implications Working Group, is focused on the second part of our charge, and I quote, "to address some of the ethical dilemmas that may be raised by the application of neuroscience research findings."

So you might think of this as the first, what's the ethics that has to go into neuroscience research from the beginning, and the second is what are some of the ethical issues that are raised by the actual neuroscience research and what people see as its implications.

We'll hear updates from both working groups this morning, and Christine Grady will start us off with an update from the Research and Integration Working Group.

Christine.

## SESSION 1

DR. GRADY: Thank you, Amy.

So my task is, as you heard, to report on the progress of the Neuroscience Research and Integration Working Group, and I want to first acknowledge my working group members: Amy Gutmann, James Wagner, Nelson Michael, Raju Kucherlapati, Barbara Atkinson, and John Arras.

As you heard already, our working group is focusing on the first part of the President's charge to the Commission, and that is, again in quotes, "to identify proactively a set of core ethical standards to guide neuroscience research."

We met as a working group in December. At that meeting, we explored how modern neuroscience might give rise to novel ethical questions and considered how

core ethical standards might be integrated across the life of the research endeavor and explored ways to better integrate ethics into science education and practice.

We're also reviewing common rule requirements to determine whether or not special emphasis or clarification might be needed, given the nature of neuroscience research.

So this morning I'm going to just highlight our group's discussions related to the conceptual foundations and possible approaches to early integration of ethics and neuroscience. As a result of the discussions that we had, we propose -- and you have already heard this from Dr. Gutmann -- that the Commission consider releasing an initial report, a Part 1 report, on this project specifically focusing on ethics integration.

We anticipate that other aspects of our discussion, for example, the initial consideration about research regulations, will continue at a later time and will continue to inform the discussions of the Commission on this issue.

So, first of all, we at the working group acknowledged that, in general, the ethical issues that are encountered in neuroscience are not necessarily unique to neuroscience, but some of them might be expressed in greater relief. And partially that's because investigating the brain raises questions about the brain's relationship to the mind, the brain's relationship to what makes us human, and a number of things that are sort of deep and complex.

Neuroscience also has the potential to find interventions that might prevent or treat many devastating neurological disorders that we are now facing as a society and as a world, including dementia of various types, especially Alzheimer's, Parkinson's disease and a variety of mental illnesses.

Because of these kinds of associations, because of the way that

neuroscience investigates the brain and the mind, ethical issues such as those related to intellectual and emotional privacy, for physical or mental volition might be heightened or at least perceived to be heightened.

And then other issues, such as diminished capacity to consent, are going to be encountered in neuroscience research since it often concerns conditions of neurological impairment.

Neuroscience, we thought, could provide a lens through which to consider some of these ethical issues in a way that's relevant to scientists in a wide variety of disciplines. It doesn't have to be only limited to neuroscience, and so we discussed the sort of desirability of integrating ethics into the science from the beginning of the trajectory all the way through, and we talked about possible models of ethics integration.

So, first of all, we recognize that many different parties have responsibility for and interest in integrating ethics throughout the research process. These range from public and private institutions funding research to individual investigators who have an interest in this as well.

And there are several possible models that we thought of, of how ethics might be integrated into science and how it might be organized and administered, and as well as various approaches to ethics integration, such as, for example promoting parallel research on ethics issues alongside with the neuroscience, implementing ethics consultation into the scientific enterprise, and/or including an ethicist or a scientist with ethics experience or expertise on the research staff, on the research team.

Institutions and individuals involved in the research process will need to sort of assess which strategies work best for them in their context, and we recognize that

different contexts might call for different models. Some institutions or investigators might employ one of those that we discussed. Some of them might employ a variety of them or something entirely different.

We also recognize that it's critical that there be adequate financial and other resources for the possibility of integrating ethics into this process.

So at the moment we're anticipating that the working group will meet again to consider the common rule requirements and determine whether or not special emphasis or clarification is needed, given the specific nature of neuroscience research and the core ethical standards that the Commission supports.

And for today, we propose that the Commission consider the following:

The possibility of disseminating a first report in response to the President's charge that focuses on early ethics integration to support both good ethics and good science throughout the research process, and that report ideally will contain salient examples of how ethics integration can foster robust science.

The Commission might also consider recommendations that suggest that institutions and organizations provide sufficient funding and other resources for this kind of ethics integration and funding and resources also to support ethics integration through both theoretical and empirical research that might explore the development, the implementation, and the effectiveness of such integration.

CHAIR GUTMANN: Thank you.

So let me just frame what Christine has just outlined very clearly in why one of the first things Christine said which we're underlining is that in focusing on the ethics of neuroscience research, we are not saying or implying that there is more concern about ethics in neuroscience than in any other scientific endeavor. So then it

may raise the question why are we focusing on the ethics of neuroscience.

And there is a formal and a substantive answer to that. One is the formal answer is we were asked by President Obama in this new Brain Initiative to do this. But there's a substantive answer to that, too, and that is that in the United States and worldwide the burden of neurological disorders is high and it's projected to increase substantially in the years to come and the estimated neurological disorders to affect as many as one billion people globally and millions of people in the United States, and these disorders are found across every age group, across every region, and the brain is our least well understood organ.

So the research needed in neuroscience is enormous, and it is worthy of the focus. We also know as a Bioethics Commission that when you do cutting edge research, it surges ahead when you have findings, now, and the findings are slow to come. You often don't know, and it can come to a grinding halt if there's one significant ethical lapse.

And so our focus is really quite the opposite of raising a red flag and saying, "Oh, oh, there's something wrong here." It is say, "Let us be proactive. Let us work with the neuroscience community." We have some neuroscientists on our Commission, Stephen Hauser, for example. Let us work together. Let us hear from scientists. Let us hear from members of the concerned public. Let us hear from legal scholars and ethicists, and let us come forward with operationalizable recommendations that can bring the basic standards of ethics into a science that is a relatively new science, and let's think about what models work best here.

Now, Christine also mentioned an important fact, and we have an actual quote from somebody who spoke to the Commission earlier that I think sums it up very

well if I can find it. I will paraphrase it if I can't, but basically, the quote is or the summary of the quote is that when you're working with the brain, there's a particular understandable sensitivity -- here it is -- Terrence Sejnowski: "By virtue of having a brain, you have a memory. By virtue of having a memory, you have a personal narrative, and these are the things that are devastated by Alzheimer's, and we're trying to understand what goes wrong. In order to do that, we need to go to the physiology and we need to be able to develop these new neural techniques, and that makes it a very much more challenging enterprise than helping the heart or the liver, you know. It's important for saving lives, but somehow when you start tinkering with the brain, people get a little bit more concerned because it's really tinkering with who you are, and that's I think something we're all grappling with."

And that underlines our considerations for understanding the heightened, if you will, both subjective and objective concern about the ethics of neuroscience.

So thank you, Christine, for summarizing what we're thinking about as far as recommendations, and I really want to open it up for other members of the Commission. Jim, first, and any, you know, any comments that anybody has, questions and comments. Great.

Jim.

VICE CHAIR WAGNER: Christine, thank you for that, and to the whole working group, and I think we're going down just the right path.

Amy, I'd like to amplify on a point you made, and it's a point that the working group has discussed, but I would like to comment or at least suggest something different about the order in which we discuss it, and that is this notion about good ethics and good science, and then we always say as a second comment that good ethics fosters

good science.

I'd like to see us flip that. Otherwise we have this notion I'm sure in a PI's mind that the role of ethics is to be regulatory. It's to set certain restrictions as opposed to understanding ethics as a companion discipline to the excellence of what's done.

It's funny. You mentioned the word "lens," ethics is a lens. It made me think of astronomers. You know, astronomers are not physicists or optics designers, but they understand that optics of a telescope is an important companion discipline that both restricts their ability to look at what they're looking at and about which they also hope it will improve.

If we could by the way we communicate this try to impart some sense of ownership to our PIs of the urgency to improve ethics, if you will, rather than just being restricted by it. Do you see what I'm saying? I'd love to see that be the tone, something early in the tone of our report.

CHAIR GUTMANN: Sure. Go ahead.

DR. GRADY: I love that analogy, Jim, about the lens because I think I agree with you. I think what we talked about and what we've talked about in other reports as well is, you know, ethics and science are inextricable from each other, and the way to think about the ethics of science is not just in restricting it, but in promoting it and enhancing it and making it better.

VICE CHAIR WAGNER: And being impatient for its improvement.

CHAIR GUTMANN: May I just ask Dan to introduce himself? We're very happy you just arrived.

DR. SULMASY: Dan Sulmasy from the University of Chicago. Happy to have arrived.

CHAIR GUTMANN: Great. Raju.

DR. KUCHERLAPATI: Thank you. Christine, thank you.

I want to make a couple of general comments, and I want to make a specific comment.

So the general comment is that although, you know, the President asked the Commission to think about the ethics and neuroscience, the context was in terms of the Brain Initiative, which is the mapping of the brain, which is only a small part of neuroscience, and actually it's wonderful that the Commission is thinking about this in a much broader context of not just in the Brain Initiative, but neuroscience in general and all science in a much broader sense because, like Amy said, many of the principles that we talked about are applicable to a variety of different issues. That's number one.

Number two is that the request is actually, and the work that the neuroscience community and this Commission representing perhaps the ethics community is extraordinary because there are many scientific enterprises even in recent memory, a broad scale that could have implications for ethics, and they never really started simultaneously.

In many instances the science started and moved ahead, and sometimes, you know, problems were identified through the science, and then the ethics community came in. So it is also doing catch-up, and I think there's an opportunity here that instead of doing such catch-up that actually that we could move, you know, a large step, which is also very excellent.

Now, the specific comment, Christine, that I want to make is the following: that, you know, to be able to have, you know, neuroscience and ethics to be, you know, or to go in lockstep, it is important for us to recognize that at every academic

institution or other research institution, there is a fairly large community of neuroscientists, you know, both basic scientists and physicians who are doing research and so on.

And the ethics community that could potentially support them is actually tiny, you know, and the ratios are abnormally bad.

So one of the things that we really need to be thinking about is, you know, obviously I don't think that we could make a recommendation and say let us, you know, go and hire 100 ethicists or so who would be able to help this enterprise because that would be impractical to do. Even if we wanted to, they probably will not be able to get, you know, that many well qualified people.

But how do we with the resources that institutions have to be able to grow in a reasonable fashion, to support this enterprise, and how could we help them today?

And so one of the things that I think we'll talk about later is that whether, you know, this idea of like a roving ambassador or many institutions have like, you know, core facilities, such as my institution would have. If I wanted to do electron microscopy, then I go someplace, or if I want to be able to get help with statistics, I go someplace else, and if I want to have DNA sequenced, I may go someplace else.

And those kinds of facilities actually serve a wide spectrum of researchers, and whether there is a mechanism that we could think about that would actually help people to be able to think about the problems and help them in ethical deliberations that might be involved in their research.

CHAIR GUTMANN: So a core bioethics facility would be very helpful because, as we've said, it isn't as if there's a unique set of every kind of science. There are many common threads, and there are some unique issues, but that would be really

helpful.

Christine, sure.

DR. GRADY: I agree with you, Raju, and I think it's interesting that you said, you know, so much of what has happened in ethics and science is playing catch-up. In a certain way what you're describing is what we need to do in terms of this idea of integration.

You know, there are many more neuroscientists than there are people who are knowledgeable about ethics, but there are these interesting models that you've described one that, you know, work in institutions where you can have a source of expertise to go seek help from.

There are also, you know, public engagement models. There are community advisory boards. There are research ethics consultation services. I mean, there are lots of models that are sort of springing up in different places, but they're all very small and very new in many respects.

So you know, maybe the Commission's idea that there needs to be resources behind this idea is one important factor, but the other thing is recognizing that, you know, education way back at the beginning or I don't know where the beginning is, but somewhere early in people's training and education, ethics needs to be integrated there as well so that there are different ways to --

CHAIR GUTMANN: So there are two different sets, if you will, just to simplify greatly, but let me simplify greatly. There are two different sets of ethical needs in scientific research. One, let's say, are very basic, informed consent, for example. And in most research with human subjects, it doesn't raise tremendously new or difficult issues, and those kinds of education, that kind of education really needs to be

done earlier in the careers or scientists ideally.

And then there is a second kind of issues, which are really tough issues that anybody should think long and hard about before you move forward, and those kinds of issues you should have a kind of place to go to group to deliberate about those and make sure you get them right.

And that is why I think we're likely to recommend both education that's early in the stages of scientific career, and also something along the lines that Raju has pointed to. That's just to keep us on track of our thinking through these deliberations.

And, Nelson, you're next and, Nita, you're after Nelson.

DR. MICHAEL: So I was going to raise two issues. One is the need for the development of human capacity to support this integration. I think that has been nicely discussed by Raju and by others, but I think the other side of the coin, and we have discussed this in previous iterations of bringing in ethics during the entire life cycle of a research enterprise is bringing ethicists onto a research team is still a little counter-culture. There are certain fields that I think increasingly are doing it, but there are a lot of fields, especially the more fundamental research that you get into where a research team will probably find that a challenge in terms of how that individual sits down when you're dissecting really complex in molecular mechanisms of neurobiologic pathways.

That may be something where a research leader or a research team member doesn't feel that it is value added to really spend that time or especially if he has to spend the resources. Instead of asking three specific aims you only get two because now they're adding on a shoestring budget, they're adding additional individuals where that person has bioethics, you know, input.

So I think we're going to need to socialize this concept with the research community. Putting funding into place will definitely help with human capacity, but I think they're going to need to be a period of education so that research teams value that integration.

CHAIR GUTMANN: Could I just ask are you suggesting -- or I hope you're not suggesting -- that every research scientific research team needs an ethics specialist on it because that does seem to me a waste of resource.

DR. MICHAEL: Yes.

CHAIR GUTMANN: I mean as long as scientists have fundamental ethics education, in most cases you don't need to be sitting with an ethicist, a specialist. So can you be a little bit more specific?

DR. MICHAEL: Yeah, what I'm talking about is there needs to be increased sensing function as we do this research integration. We have ethical review committees. We call them institutional review boards in our country. We have community advisory boards.

So for the kind of research that increasingly touches people in a more direct clinical way, yes, these will be the areas where you are going to have to have a more direct integration of bioethics.

But what I see going forward is that the divide between truly fundamental research and varied clinical research is becoming increasingly blurred. So I just think that we need to keep our eye on that process, and increasingly there is going to need to be more seepage of bioethics input into projects that I think that initially we would conceive of only being fundamental.

I think that is where that theory of education is going to be required. What

I'm not talking about is if we're asking, you know, for a research team of four to have a bioethicist always on board.

CHAIR GUTMANN: I just wanted to make sure we clarified that because -- sure.

VICE CHAIR WAGNER: Yes. Thank you for clarifying that.

In fact, this, I hope, goes further. I would hope that the recommendation even when we do think it's appropriate to include ethicists on board, is not misinterpreted as absolving the PI from a responsibility for understanding something about ethics.

Given that we expect PIs to know more and more about ethics, the need, particularly in more fundamental research, for a specific ethics specialist may be obviated also.

CHAIR GUTMANN: Nita.

DR. FARAHANY: So I agree with everything we've said so far about different possible models for integration. What I find in a lot of conversations with neuroscientists is that they're very interested in making sure that they integrate ethics, but that's easier said than done without having effective models of what that looks like.

And so we've mentioned a few of them here, but I think this might be an opportunity for us to be far more specific than we've been in the past to describe what ethics integration looks like at different stages of the research process because I think early in the research process there's a model that unfortunately has come to mean very much checking a box about getting through an Institutional Review Board about making sure that the protection of subjects is appropriate and adequate and takes into consideration the risks and benefits of the research.

But a broader model that's an ongoing conversation, you know, we've mentioned early education of scientists to ensure that they actually have adequate training. I think that is great and something specific that when we get to the point of recommendations, we should be specific about it.

I would like for us to be much more specific generally about spelling out different models and even mapping different models that might be appropriate in different contexts to say, you know, here are some suggestions not meant to be constraints, but ways in which you specifically can do this, and to the extent that resources are inadequate, being able to identify specific areas of funding priority in order to increase both education of scientists and education from the earliest stages, as well as where it's really essential to have if it's an ethicist or a group or an ethics consult involved in the process.

But I think what I've heard most frequently is a strong desire to integrate ethics without clear understanding of how operationally that could occur.

And the second is it's great to say that we need to have funding resources, but again, from whom are those funding resources going to come? How are we going to prioritize it? And how might that occur?

So one big problem in neuroscience is that there isn't funding for ethics right now. There really isn't any source to whom neuroethicists can turn in order to be funded for their grants. There are some private foundations who have done great things in specific areas like Templeton has done some funding and the MacArthur Law and Neuroscience project has done some funding, but there's almost no public funding that's available even though there was some that was available for ELSI research, for genomics research. There's none with neuroscience.

And so I hope that we can be far more specific about what kinds of funding priorities we mean as well because one reason, Raju, to your point that there are so few ethicists is that there is so little funding that's available to actually have ethicists. So to the extent that the brain initiative is meant to be a public and private partnership, I think we need to identify public funding sources, as well as private funding sources that we think could make that happen.

CHAIR GUTMANN: Let me underline something that's built here that I think we really do want to put in the preliminary report based on what everybody has said. We should be as specific as possible in laying out a model. It doesn't need to be the only model, but a model of how it is feasible to integrate ethics into neuroscience research, beginning with early education that isn't or may not be unique to scientists that we think that everybody who is potentially going into professional life should have and how that could work.

I think that's really important, and if we, you know, can agree that there is a model that works, we should set it out, and it doesn't have to be a unique model, but it's important to have that.

The second thing which has come up is that any model is going to require some resources to actually make sure that people are trained in the case of neuroscience in the ethics of neuroscience. So there I think it's really important. Asking for funding shouldn't precede making clear what the need is, but we should have it. And I think that's just important.

I saw Steve.

DR. HAUSER: Thank you.

I think one of the reasons why neuroscience is so exciting, apart from its

opportunity to actually make really impactful changes in how we can help people with neurologic diseases, is that modern science has brought together behavioral science and molecular and cellular science in a way over the last few years that we couldn't have imagined.

And with that some of the clinical distinctions between psychiatry and other neurosciences, for example, have shrunk some, and these are in some respects accidents of history.

So many neuroscientists are interested in exploring such things as our emotions, attention, memory, motivation, craving, aggressiveness, these very basic human characteristics because they go awry in brain disease, in dementias, for example, as well as in some traditional psychiatric diseases.

So I think in the neuroscience community one positive feature that we have is a great interest in these problems and also in their implications for real people who suffer from disorders of these problems and also pockets of perhaps expertise in ethics within the neuroscience community that need to be nurtured as we think about the larger, you know, goal of having a stronger ethical support system in place.

CHAIR GUTMANN: Dan.

DR. SULMASY: Thanks.

I hope these aren't things that Christine already covered perhaps when I wasn't here, but I'd be concerned particularly in terms of some of the conversation we've had before that we address both the sort of overarching ethical issues in neuroscience as well as the integration and not make it one against the other, and make sure that if we're talking about funding, that we're thinking about both dimensions as well.

And then with respect to the integration, which I think would be

something novel and important, we also ought to try to do it in a way that creates incentives for the local investigators to be creative at the local level in doing this.

So I like, for instance, the idea of Raju saying that to do that they need capacities, so maybe having, you know, core bioethics centers at places to get a certain level of NIH funding or whatever for that, but also ways in which they have an option so that it doesn't sort of come out of the funding of the core science and add it on that any grant, for instance, would be able to get an extra one percent or something to do, or two percent, to get an integrated model of ethics into the project.

So that may not be the exact model, but I think something like that that sort of doesn't specify what it is, not RFAs for things, but actually giving local investigators at the local level with their own scientific creativity both the capacity to integrate and a funding incentive to do the integration at the local level and then not neglecting the possibility there would be funding for ethics that would be overarching and not confined to a particular project.

CHAIR GUTMANN: I'm going to wrap this session up and turn it over to Jim to talk about the applications group.

I do want to underline that when any government agency puts as a priority that ethics be integrated into a project, it is important that when there is funding, there's funding for ethics research, and as we know, ethics research isn't one of the costliest things in the world. There are no wet labs necessary, but it is important that a level of funding that actually does two things, that allows it to go forward and also makes it clear that we're not just talking about the importance of ethics, but actually carrying it out.

And I think that's really important, and as Lisa knows, I've conveyed that,

for example, to NIH which has Ethics as one of its priorities, but then in the funding priorities, ethics was not there, and I do think NIH gets it and will respond appropriately, but it's really important because otherwise we can't move it forward as a society in this really important initiative.

So thanks, Christine, and I'm going to turn it over to Jim now for the next part of our deliberations. Jim.